Wyeth Pharmaceuticals
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Marietta, PA 17547

Dennis J. Foley, Ph.D.
Assistant Vice President
Worldwide Regulatory Affairs

Wyeth

December 23, 2002

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

LTC John D. Grabenstein, RPh, PhD
Deputy Director for Military Vaccines
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258

Re: Letter Foley to Becher/Grabenstein, October 30, 2002

Dear Mr. Becher and LTC Grabenstein:

I refer to my letter of October 30, 2002 which advised you of the approval by the Food and Drug Administration (FDA) of Biological License Application (BLA) Supplement 101106/5015 for a new 100-dose kit of Smallpox Vaccine Dryvax®. In that communication I also explained why vaccine could be stored for 30 days at 2-8°C after reconstitution even though the product labeling that accompanies the new kits states that reconstituted Dryvax®. "may be used for 15 days if stored at 2-8°C when not in actual use".

The purpose of this letter is to inform you that on December 20, 2002, FDA approved additional data submitted by Wyeth in BLA Supplement 101106/5020 and the product may now be stored at 2-8°C for 60 days after reconstitution.

Please note that the date of reconstitution should be recorded directly on the vial label in the space provided. Unused vaccine should be discarded if more than 60 days has elapsed since reconstitution.

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We ask that you include a copy of this letter with the subsequent distribution of each kit to notify end users that the vaccine may be stored at 2-8°C for 60 days after reconstitution. We also ask that you communicate this change to end users who have previously received the product.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc: A. Criswell (Wyeth)
M. Mansoura (HHS)
D. Staten (CBER)